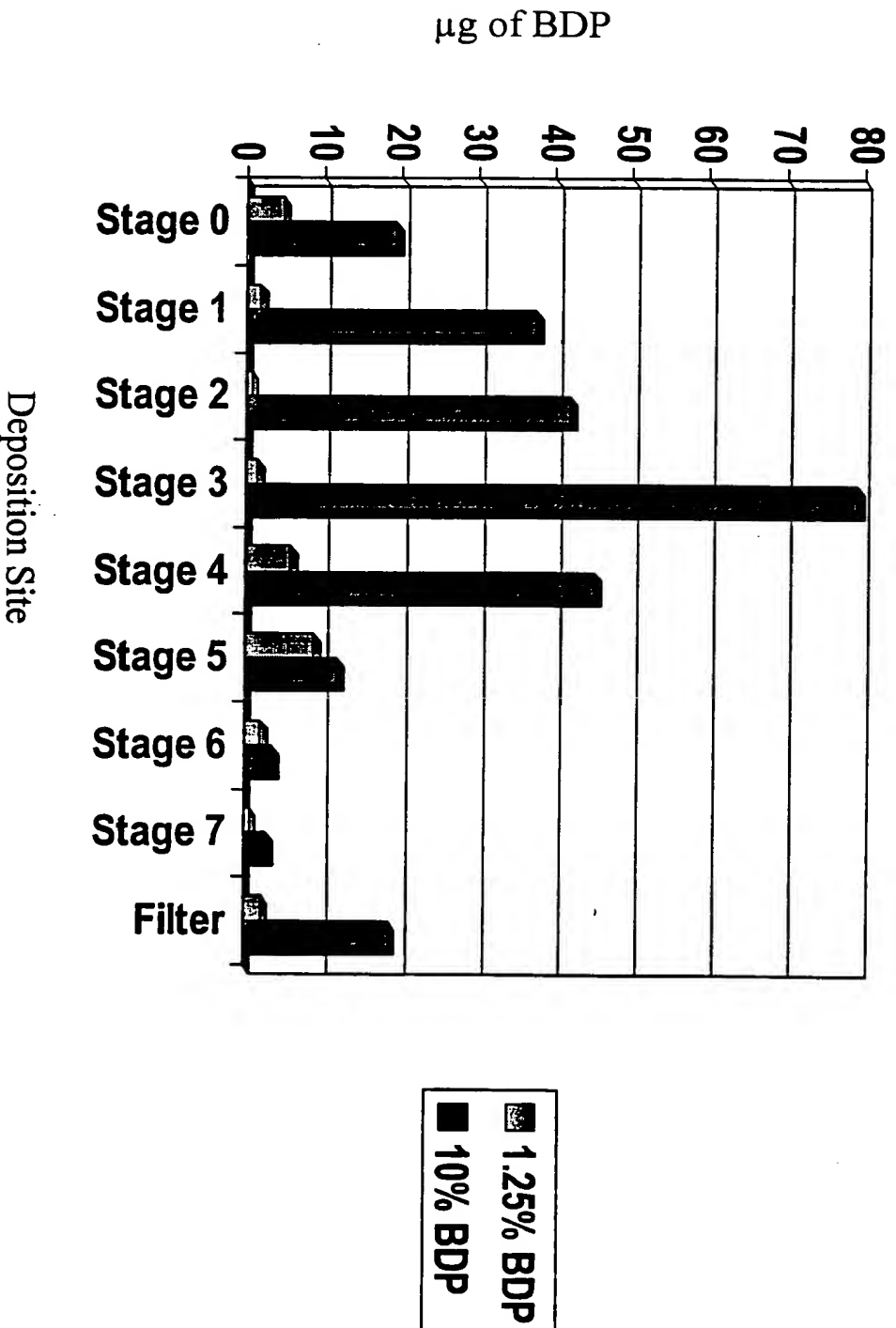


FIGURE 1

In Vitro Deposition Pattern of Aerosolized BDP Dispersions



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FIGURE 2

In Vitro Deposition Pattern of

Nanoparticulate BDP Suspensions

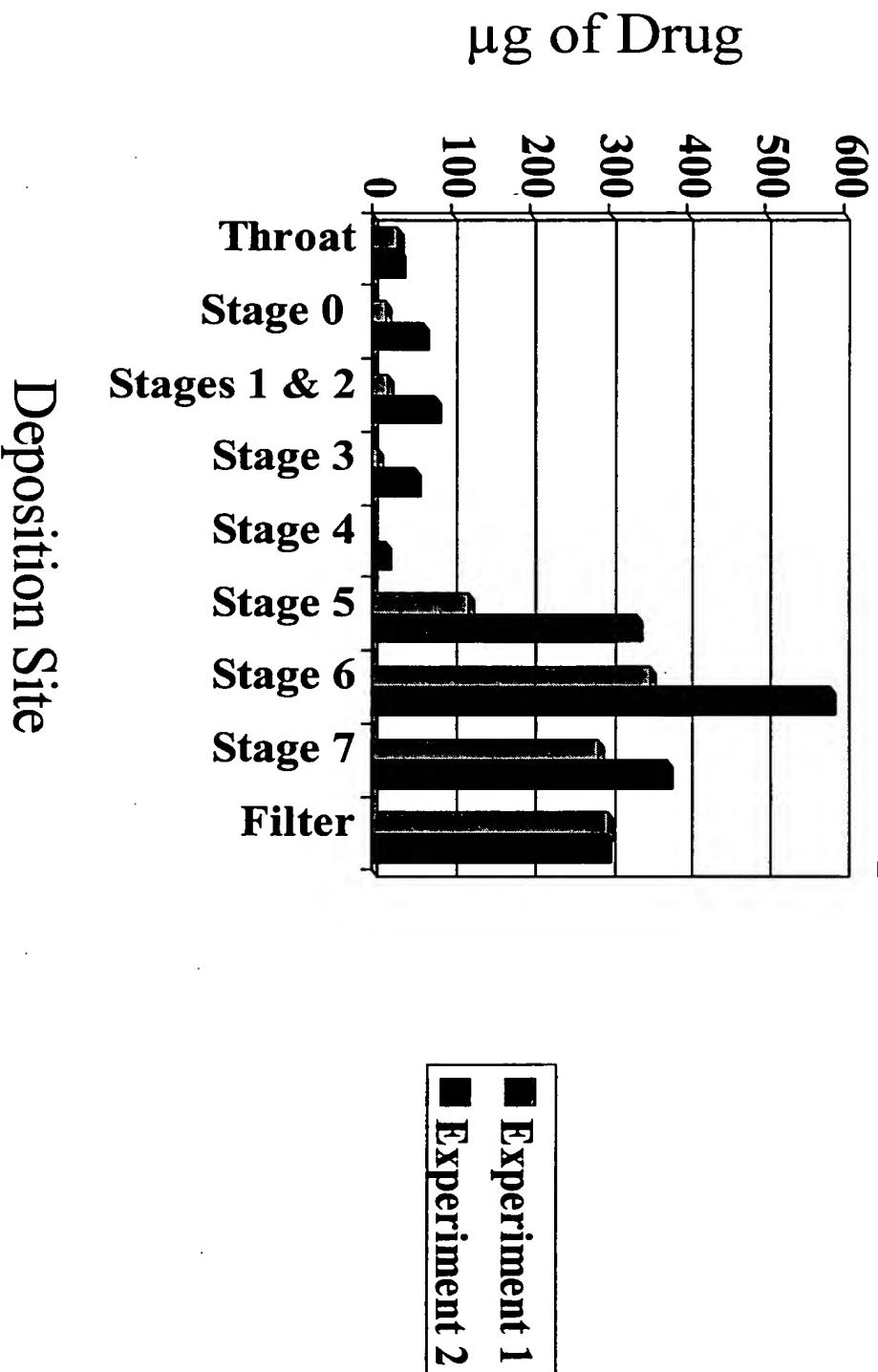
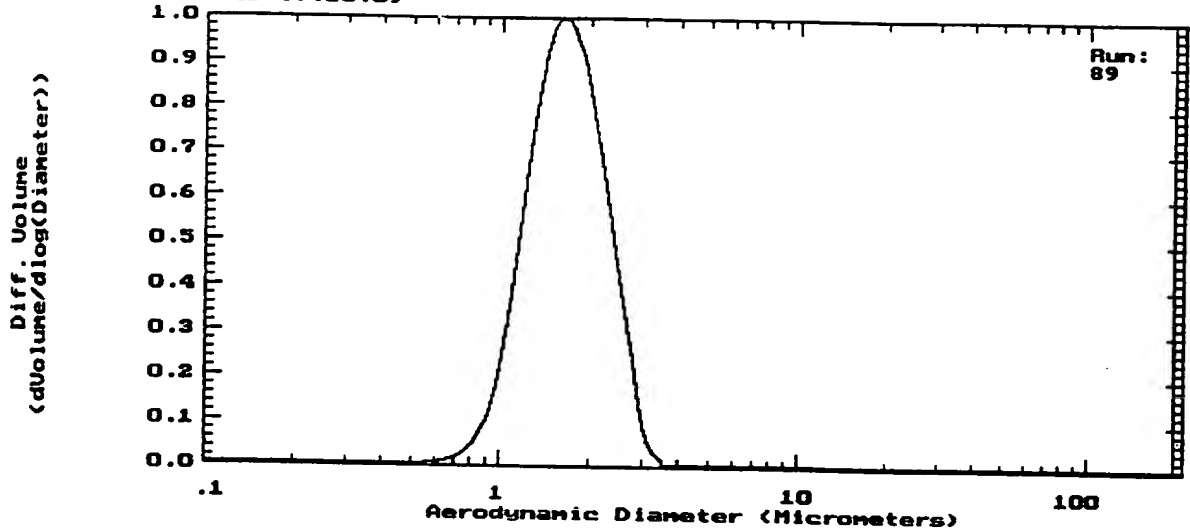


FIGURE 3

API AEROSIZER-LD V7.10.09



SPRAY-DRIED NAPROXEN

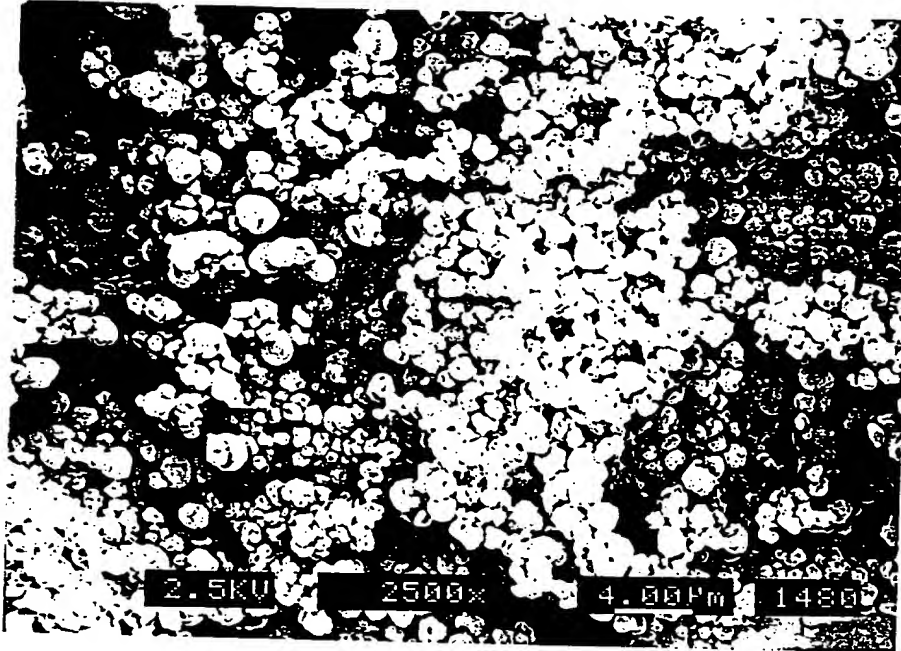
Volume Distribution by Aerodynamic Diameter

STATISTICS				PARAMETERS		%UNDER	SIZE	%UNDER	SIZE
Mean Size	:	1.671		Material	:	SDI-naproxen		10%	1.157
Standard Deviation	:	1.334		Density	:	1.26		50%	1.675
D(4,3)	:	1.740		Run Length (sec)	:	123.9			
D(3,2)	:	1.602		PMT Voltage	:	1100.0			
Mode (Log Scale)	:	1.65		Sum of channels	:	46211			
Specific Surface Area	:	2.97	sq meter/g	Lower Size Limit	:	0.10			
				Upper Size Limit	:	200.00			
				Nozzle Type	:	700um			
				Baseline Offset	:	0.10			
				Noise Filter	:	6.00			
				Regularization	:	Low			

UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER
		100	0.0000	86.0	100.00	10.0	0.0000	8.60	100.00	1.00	2.4683	0.86	1.2857		
		86.0	0.0000	74.0	100.00	8.60	0.0000	7.40	100.00	0.86	0.8394	0.74	0.4463		
		74.0	0.0000	63.0	100.00	7.40	0.0000	6.30	100.00	0.74	0.3050	0.63	0.1413		
		63.0	0.0000	54.0	100.00	6.30	0.0000	5.40	100.00	0.63	0.1042	0.54	0.0371		
		54.0	0.0000	46.0	100.00	5.40	0.0000	4.60	100.00	0.54	0.0333	0.46	0.0038		
		46.0	0.0000	40.0	100.00	4.60	0.0000	4.00	100.00	0.46	0.0036	0.40	0.0003		
		40.0	0.0000	34.0	100.00	4.00	0.1153	3.40	99.885	0.40	0.0003	0.34	0.0000		
		34.0	0.0000	29.0	100.00	3.40	1.7044	2.90	98.180	0.34	0.0000	0.29	0.0000		
		29.0	0.0000	25.0	100.00	2.90	6.4095	2.50	91.771	0.29	0.0000	0.25	0.0000		
		25.0	0.0000	22.0	100.00	2.50	9.8151	2.20	81.956	0.25	0.0000	0.22	0.0000		
		22.0	0.0000	18.0	100.00	2.20	22.597	1.80	59.359	0.22	0.0000	0.18	0.0000		
180	0.0000	160	100.00	18.0	0.0000	16.0	100.00	1.80	15.436	1.60	43.923	0.18	0.0000	0.16	0.0000
160	0.0000	140	100.00	16.0	0.0000	14.0	100.00	1.60	16.757	1.40	27.166	0.16	0.0000	0.14	0.0000
140	0.0000	120	100.00	14.0	0.0000	12.0	100.00	1.40	14.681	1.20	12.484	0.14	0.0000	0.12	0.0000
120	0.0000	100	100.00	12.0	0.0000	10.0	100.00	1.20	8.7303	1.00	3.7540	0.12	0.0000	0.10	0.0000

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FIGURE 4



Spray Dried Nanoparticulate Naproxen

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B52FF" 8ET06T60

Year	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100
1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	

API AEROSIZER-LD U7.10.09



SPRAY-DRIED NAPROXEN

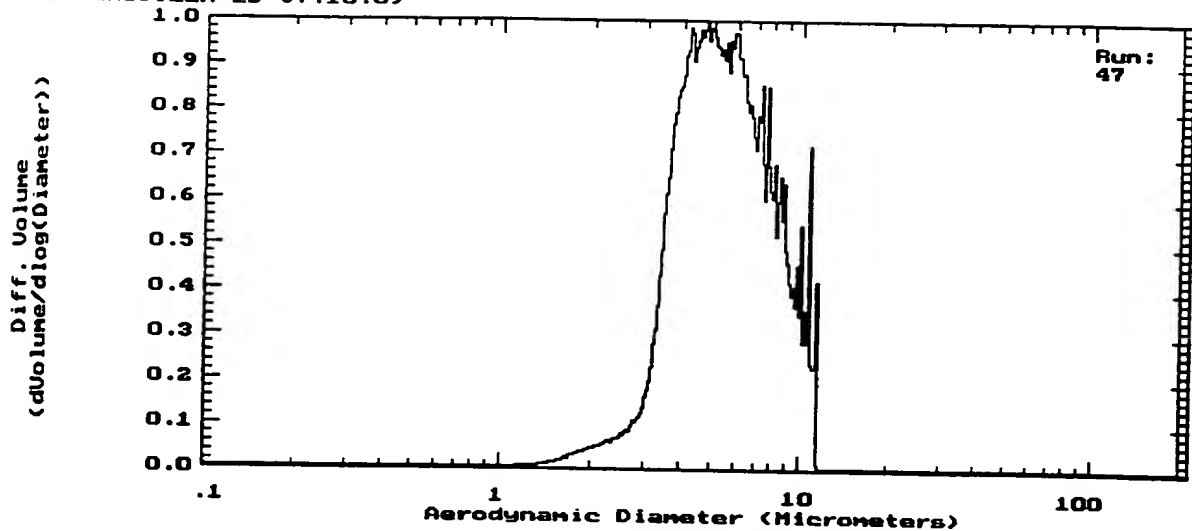
Volume Distribution by Aerodynamic Diameter

STATISTICS		PARAMETERS		%UNDER	SIZE	%UNDER	SIZE
Mean Size	: 2.906	Material	: SDI-naproxen	10%	1.554	90%	4.651
Standard Deviation	: 1.524	Density	: 1.26	50%	3.183		
D(4,3)	: 3.142	Run Length (sec)	: 108.9				
D(3,2)	: 2.632	PMT Voltage	: 1100.0				
Mode (Log Scale)	: 3.66	Sum of channels	: 13520				
Specific Surface Area	: 1.81 sq meter/g	Lower Size Limit	: 0.10				
		Upper Size Limit	: 200.00				
		Nozzle Type	: 700um				
		Baseline Offset	: 0.10				
		Noise Filter	: 6.00				
		Regularization	: Low				

UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER
				100	0.0000	86.0	100.00	10.0	0.0000	8.60	100.00	1.00	1.0101	0.86	0.6844
				86.0	0.0000	74.0	100.00	8.60	0.0000	7.40	100.00	0.86	0.4335	0.74	0.2509
				74.0	0.0000	63.0	100.00	7.40	0.0000	6.30	100.00	0.74	0.1785	0.63	0.0723
				63.0	0.0000	54.0	100.00	6.30	1.1614	5.40	98.839	0.63	0.0548	0.54	0.0175
				54.0	0.0000	46.0	100.00	5.40	9.8645	4.60	88.974	0.54	0.0153	0.46	0.0021
				46.0	0.0000	40.0	100.00	4.60	13.706	4.00	75.268	0.46	0.0020	0.40	0.0001
				40.0	0.0000	34.0	100.00	4.00	18.274	3.40	56.994	0.40	0.0001	0.34	0.0000
				34.0	0.0000	29.0	100.00	3.40	15.715	2.90	41.278	0.34	0.0000	0.29	0.0000
				29.0	0.0000	25.0	100.00	2.90	10.821	2.50	30.457	0.29	0.0000	0.25	0.0000
				25.0	0.0000	22.0	100.00	2.50	7.2247	2.20	23.232	0.25	0.0000	0.22	0.0000
				22.0	0.0000	18.0	100.00	2.20	8.6259	1.80	14.606	0.22	0.0000	0.18	0.0000
180	0.0000	160	100.00	18.0	0.0000	16.0	100.00	1.80	3.7744	1.60	10.832	0.18	0.0000	0.16	0.0000
160	0.0000	140	100.00	16.0	0.0000	14.0	100.00	1.60	3.5448	1.40	7.2871	0.16	0.0000	0.14	0.0000
140	0.0000	120	100.00	14.0	0.0000	12.0	100.00	1.40	3.1759	1.20	4.1112	0.14	0.0000	0.12	0.0000
120	0.0000	100	100.00	12.0	0.0000	10.0	100.00	1.20	2.4167	1.00	1.6945	0.12	0.0000	0.10	0.0000

FIGURE 6

API AEROSIZER-LD U7.10.09



spray dried ta

Volume Distribution by Aerodynamic Diameter

STATISTICS		PARAMETERS		%UNDER	SIZE	%UNDER	SIZE
Mean Size	: 5.540	Material	: SDI-naproxen	10%	3.600	90%	9.082
Standard Deviation	: 1.455	Density	: 1.26	50%	5.516		
D(4,3)	: 5.924	Run Length (sec)	: 189.6				
D(3,2)	: 5.146	PWT Voltage	: 1100.0				
Mode (Log Scale)	: 4.82	Sum of channels	: 100494				
Specific Surface Area	: 0.93 sq meter/g	Lower Size Limit	: 0.10				
		Upper Size Limit	: 200.00				
		Nozzle Type	: 700um				
		Baseline Offset	: 0.10				
		Noise Filter	: 6.00				
		Regularization	: Off				

UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER	UPPER SIZE	% IN	LOWER SIZE	% UNDER
		100	0.0000	86.0	100.00	10.0	7.5026	8.60	86.677	1.00	0.0237	0.86	0.0213		
		86.0	0.0000	74.0	100.00	8.60	10.326	7.40	76.352	0.86	0.0121	0.74	0.0092		
		74.0	0.0000	63.0	100.00	7.40	13.417	6.30	62.935	0.74	0.0064	0.63	0.0028		
		63.0	0.0000	54.0	100.00	6.30	14.999	5.40	47.935	0.63	0.0021	0.54	0.0006		
		54.0	0.0000	46.0	100.00	5.40	16.094	4.60	31.841	0.54	0.0006	0.46	0.0001		
		46.0	0.0000	40.0	100.00	4.60	13.547	4.00	18.295	0.46	0.0001	0.40	0.0000		
		40.0	0.0000	34.0	100.00	4.00	11.255	3.40	7.0394	0.40	0.0000	0.34	0.0000		
		34.0	0.0000	29.0	100.00	3.40	3.2799	2.90	3.7595	0.34	0.0000	0.29	0.0000		
		29.0	0.0000	25.0	100.00	2.90	1.3355	2.50	2.4240	0.29	0.0000	0.25	0.0000		
		25.0	0.0000	22.0	100.00	2.50	0.8131	2.20	1.6109	0.25	0.0000	0.22	0.0000		
		22.0	0.0000	18.0	100.00	2.20	0.8995	1.80	0.7114	0.22	0.0000	0.18	0.0000		
		18.0	0.0000	16.0	100.00	1.80	0.3128	1.60	0.3985	0.18	0.0000	0.16	0.0000		
		16.0	0.0000	14.0	100.00	1.60	0.1861	1.40	0.2125	0.16	0.0000	0.14	0.0000		
		14.0	0.0000	12.0	100.00	1.40	0.1061	1.20	0.1063	0.14	0.0000	0.12	0.0000		
180	0.0000	160	100.00			1.20	0.0613	1.00	0.0450	0.12	0.0000	0.10	0.0000		
160	0.0000	140	100.00												
140	0.0000	120	100.00												
120	0.0000	100	100.00	12.0	5.8201	10.0	94.180								

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FIGURE 7(A)

Spray-dried nanoparticulate budesonide

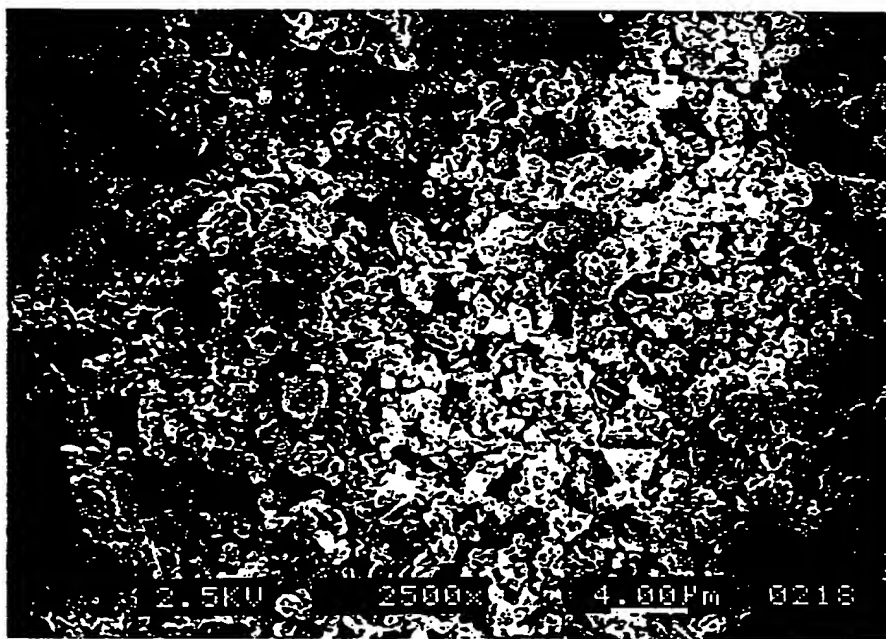
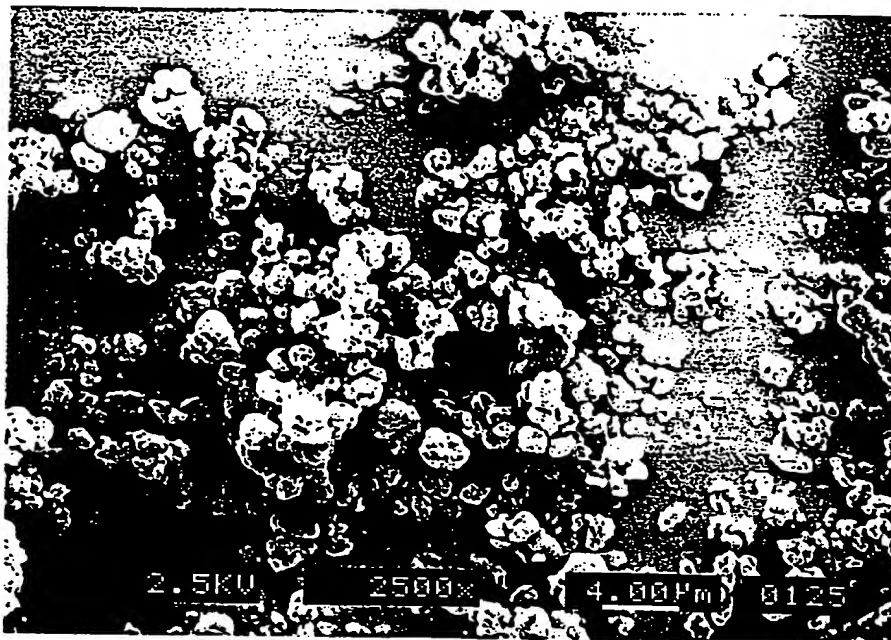


FIGURE 7(B)

Micronized budesonide

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FIGURE 8

HORIBA LA-910

Laser scattering particle size distribution analyzer

PARTICLE SIZE MEASUREMENT DATA

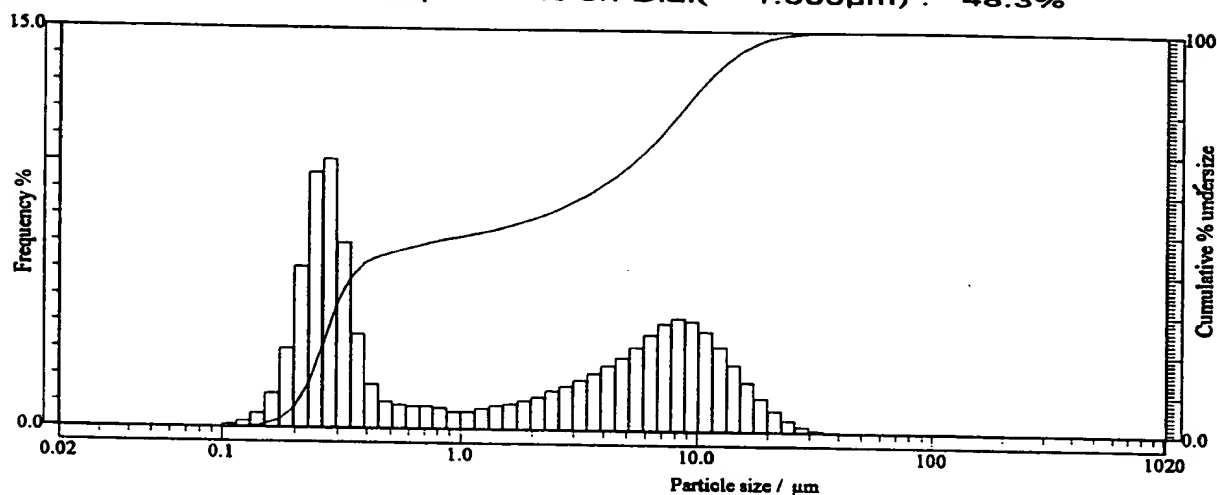
Freeze-dried Material : 5%Dextrose 4-3-98
 Source : Reconst. water/3d fill
 Lot Number : In water/1 min. sonication

Data

Median : 1.355 μ m SP.Area: 114884cm²/cm³ S.D. : 5.324 μ m
 Mode : 0.272 μ m Mean : 4.225 μ m
 C.V. : 126.02%

Span : (D 10.0-D 90.0) / D50 = 8.564

Dia. on %(90.0%) :	11.822 μ m	% on Dia.(0.400 μ m) :	41.9%
Dia. on %(50.0%) :	1.355 μ m	% on Dia.(0.300 μ m) :	31.7%
Dia. on %(95.0%) :	14.996 μ m	% on Dia.(0.100 μ m) :	0.0%
Dia. on %(80.0%) :	8.384 μ m	% on Dia.(0.200 μ m) :	5.9%
Dia. on %(70.0%) :	5.949 μ m	% on Dia.(1.000 μ m) :	48.3%



Size(μ m)	Freq(%)	Und(%)	Size(μ m)	Freq(%)	Und(%)	Size(μ m)	Freq(%)	Und(%)
1019.5	0.00	100.00	26.11	0.46	99.68	0.669	0.86	46.02
890.1	0.00	100.00	22.80	0.81	99.20	0.584	0.90	45.16
777.1	0.00	100.00	19.90	1.29	98.39	0.510	1.03	44.26
678.5	0.00	100.00	17.38	1.88	97.10	0.445	1.68	43.23
592.4	0.00	100.00	15.17	2.54	95.22	0.389	3.56	41.54
517.2	0.00	100.00	13.25	3.20	92.68	0.339	6.97	37.98
451.6	0.00	100.00	11.56	3.76	89.48	0.296	10.10	31.01
394.2	0.00	100.00	10.10	4.15	85.72	0.259	9.61	20.91
344.2	0.00	100.00	8.816	4.26	81.57	0.226	6.06	11.30
300.5	0.00	100.00	7.697	4.06	77.32	0.197	2.99	5.23
262.4	0.00	100.00	6.720	3.63	73.26	0.172	1.31	2.24
229.1	0.00	100.00	5.867	3.16	69.63	0.150	0.56	0.93
200.0	0.00	100.00	5.122	2.76	66.47	0.131	0.26	0.37
174.6	0.00	100.00	4.472	2.46	63.71	0.115	0.11	0.11
152.5	0.00	100.00	3.905	2.16	61.25	0.100	0.00	0.00
133.1	0.00	100.00	3.409	1.89	59.10	0.087	0.00	0.00
116.2	0.00	100.00	2.976	1.68	57.21	0.076	0.00	0.00
101.5	0.00	100.00	2.599	1.49	55.52	0.067	0.00	0.00
88.58	0.00	100.00	2.269	1.24	54.03	0.058	0.00	0.00
77.34	0.00	100.00	1.981	1.10	52.79	0.051	0.00	0.00
67.52	0.00	100.00	1.729	0.97	51.69	0.044	0.00	0.00
58.95	0.00	100.00	1.510	0.90	50.72	0.039	0.00	0.00
51.47	0.00	100.00	1.318	0.80	49.82	0.034	0.00	0.00
44.94	0.00	100.00	1.151	0.67	49.02	0.029	0.00	0.00
39.23	0.00	100.00	1.005	0.66	48.35	0.026	0.00	0.00
34.25	0.11	100.00	0.877	0.81	47.69	0.022	0.00	0.00
29.91	0.24	99.89	0.766	0.86	46.88			

FIGURE 9

HORIBA LA-910

Laser scattering particle size distribution analyzer

PARTICLE SIZE MEASUREMENT DATA

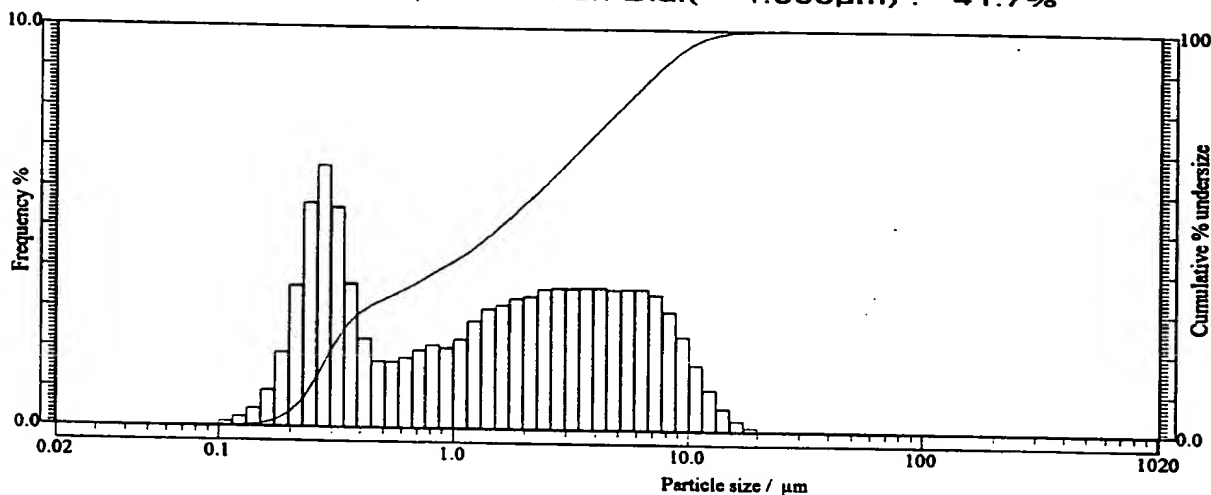
Material : reconst. 1%N9585, 5%Man
Source : in water
Lot Number : 1min sonication

Data

Median : 1.533 μ m SP.Area: 93485cm²/cm³ S.D. : 3.123 μ m
Mode : 0.276 μ m Mean : 2.767 μ m
C.V. : 112.86%

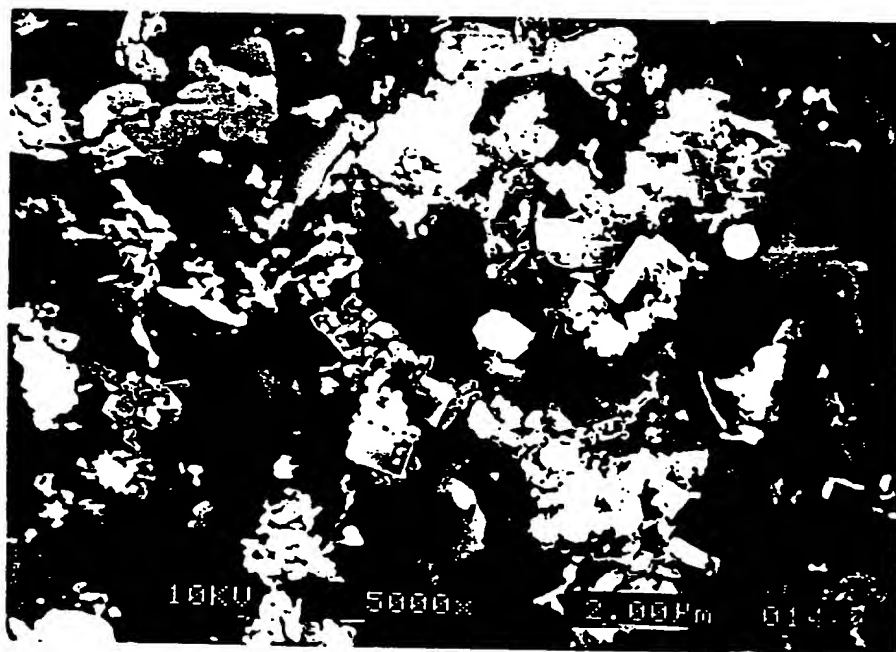
Span : (D 10.0-D 90.0) / D50 = 4.665

Dia. on %(90.0%) :	7.392 μ m	% on Dia.(0.400 μ m) :	28.8%
Dia. on %(50.0%) :	1.533 μ m	% on Dia.(0.300 μ m) :	19.8%
Dia. on %(95.0%) :	9.346 μ m	% on Dia.(0.100 μ m) :	0.0%
Dia. on %(80.0%) :	5.011 μ m	% on Dia.(0.200 μ m) :	4.0%
Dia. on %(70.0%) :	3.416 μ m	% on Dia.(1.000 μ m) :	41.7%



Size(μ m)	Freq(%)	Und(%)	Size(μ m)	Freq(%)	Und(%)	Size(μ m)	Freq(%)	Und(%)
1019.5	0.00	100.00	26.11	0.00	100.00	0.669	1.75	35.66
890.1	0.00	100.00	22.80	0.00	100.00	0.584	1.65	33.91
777.1	0.00	100.00	19.90	0.11	100.00	0.510	1.67	32.26
678.5	0.00	100.00	17.38	0.27	99.89	0.445	2.22	30.59
592.4	0.00	100.00	15.17	0.57	99.61	0.389	3.60	28.36
517.2	0.00	100.00	13.25	1.04	99.04	0.339	5.49	24.76
451.6	0.00	100.00	11.56	1.66	98.00	0.296	6.54	19.28
394.2	0.00	100.00	10.10	2.35	98.34	0.259	5.59	12.74
344.2	0.00	100.00	8.816	2.98	93.99	0.226	3.52	7.15
300.5	0.00	100.00	7.697	3.38	91.01	0.197	1.87	3.63
262.4	0.00	100.00	6.720	3.63	87.62	0.172	0.93	1.76
229.1	0.00	100.00	5.867	3.52	84.09	0.150	0.46	0.84
200.0	0.00	100.00	5.122	3.51	80.57	0.131	0.25	0.38
174.6	0.00	100.00	4.472	3.55	77.06	0.115	0.13	0.13
152.5	0.00	100.00	3.905	3.56	73.50	0.100	0.00	0.00
133.1	0.00	100.00	3.409	3.53	69.94	0.087	0.00	0.00
116.2	0.00	100.00	2.976	3.54	66.41	0.076	0.00	0.00
101.5	0.00	100.00	2.599	3.51	62.87	0.067	0.00	0.00
88.58	0.00	100.00	2.269	3.33	59.36	0.058	0.00	0.00
77.34	0.00	100.00	1.981	3.27	56.03	0.051	0.00	0.00
67.52	0.00	100.00	1.729	3.10	52.76	0.044	0.00	0.00
58.95	0.00	100.00	1.510	3.00	49.66	0.039	0.00	0.00
51.47	0.00	100.00	1.318	2.70	46.66	0.034	0.00	0.00
44.94	0.00	100.00	1.151	2.24	43.96	0.029	0.00	0.00
39.23	0.00	100.00	1.005	2.02	41.73	0.026	0.00	0.00
34.25	0.00	100.00	0.877	2.09	39.71	0.022	0.00	0.00
29.91	0.00	100.00	0.766	1.95	37.62			

FIGURE 10



**Micrograph of
Milled TA (3.6%) with Span 85 (0.5%)**

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